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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,219	10/29/2003	Herbert H. Loeffler	1159.1009-007	5251
21005	7590	05/18/2006	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				HYUN; PAUL SANG HWA
ART UNIT		PAPER NUMBER		
				1743

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/696,219	LOEFFLER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Paul S. Hyun	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 March 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4, 10, 12, 13 and 17-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-4, 10, 12, 13 and 17-24 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 06 March 2006 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/6/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Response to Amendment***

Claims 1-4, 10, 12, 13 and 17-24 are pending. Claims 1-4, 10, 12, 13, 17 and 18 were amended and claims 19-24 were added. It should be noted that the amendments made to claims 1-4, 10, 12, 13, 17 and 18 have changed the scope of the claims.

The amendments made to drawing Figure 4 has been acknowledged.

The objection to claims 2-12 and 14-18 cited in the First Office Action has been withdrawn in light of the amendments made to the claims.

The rejection of claim 10 under 35 U.S.C. 112 1<sup>st</sup> paragraph cited in the First Office Action has been withdrawn in light of the amendments made to the claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 10, 12, 13, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a conduit that houses a piston that is capable of opening a valve, does not reasonably provide enablement for a conduit capable of opening a valve. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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The Specification discloses a conduit having a piston 33 therein that is capable of opening a valve 4a (see lines 3-10, col. 13). However, the Specification does not disclose a conduit that is capable of physically opening a valve. A conduit cannot open a valve since the term conduit simply denotes a channel or an opening.

Claims 1-4, 10, 12, 13 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cover that is releasably sealed to a flat surface to define a chamber therebetween, does not reasonably provide enablement for a chamber that forms a cavity on a flat surface. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

It is not clear how a chamber can form a cavity on a flat surface just by attaching itself to the flat surface. Moreover, if a surface comprises a cavity, then it cannot be flat.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 10, 12, 13 and 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13 recite a conduit that is capable of opening a valve. It is not clear how a conduit is capable of physically actuating a valve. The term conduit connotes a channel. It does not appear that a hollow space is capable of opening a valve.

Claims 1, 13, 19 and 23 recite the limitation "a chamber forming a cavity on said flat surface, said chamber being releasably sealed to said flat surface". It is not clear how a chamber can form a cavity on a flat surface just by attaching itself to the flat surface.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 10, 12, 13, 17, 18, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al. (US 5,346,672) in view of Saxon et al. (US 4,927,765).

Stapleton et al. disclose a device for carrying out reactions of biological specimens disposed on glass slides. The device comprises a frame 19 having a plurality of grooves 21 for accommodating a plurality of glass slides. Each glass slide 18 is enclosed by flanges 46 and cover rims 40 that form a releasably sealed chamber 32 around the glass slide. The device also comprises a conical fluid port 56 located in the wall of the chamber through which fluids can be added or removed. The device also comprises a valve in the form of a plug 58 comprising a flexible bladder 60. The plug 58 acts to seal port 56 and vent chamber 32 (see Figs. 5 & 6 and lines 1-16 col. 12). The bladder 60 is also capable of holding an aliquot of reagent in the fluid port. However, the reference does not disclose a conduit or an actuator as recited in the claim.

Saxon et al. disclose an automated reagent dispenser. The reagent dispenser is adapted to pipet a reagent from a source and dispense the reagent into a receptacle. The dispenser comprises a conduit in the form of port 23 through which negative and positive pressure flows as well as an actuator that moves the dispenser to the desired location to dispense the reagent (see lines 31-41 col. 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide an automated reagent dispenser as taught by Saxon et al. to the device disclosed by Stapleton et al. such that the port of the reagent dispenser forms a seal with the desired port of the Stapleton et al. device. The dispenser would allow automation of sample and reagent transfer into the plurality of chambers of the device disclosed by Stapleton et al. See In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), a case in which the Court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is considered an obvious expedient.

It also would have been obvious to one of ordinary skill in the art to provide a second port and a second conduit to each of the chambers of the modified Stapleton et al. device so that a second reagent can be dispensed into chamber 32 of the device. See In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), a case in which the Court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al. (US 5,346,672) in view of Krug et al. (US 3,136,440) and Jackson et al. (US 5,340,541).

Stapleton et al. disclose a device for carrying out reactions of biological specimens disposed on glass slides. The device comprises a frame 19 having a plurality of grooves 21 for accommodating a plurality of glass slides. Each glass slide 18 is enclosed by flanges 46 and cover rims 40 that form a releasably sealed chamber 32. The device also comprises a conical fluid port 56 located in the wall of the chamber through which fluids can be added or removed. The device also comprises a valve in the form of a plug 58 comprising a flexible bladder 60. The plug 58 acts to seal port 56 and vent chamber 32 (see Figs. 5 & 6 and lines 1-16 col. 12). The bladder 60 is also capable of holding an aliquot of reagent in the fluid port. However, the reference does not disclose an actuator or a piston as recited in the claim.

Jackson et al. disclose an automated dispenser comprising a conduit 42 having a dispensing probe 46 therein that is adapted to puncture a sealed vial to dispense a desired amount of liquid to the vial (see Fig. 3 and lines 60-68, col. 7).

Krug et al. disclose a self-sealing pierceable stopper for sealing liquid holding containers. The stopper is adapted to be pierced by a pipet or a syringe. The stopper allows fluid to be dispensed or withdrawn from the container without exposing the fluid to the exterior environment.

In light of the teachings of Jackson et al. and Krug et al., it would have been obvious to one of ordinary skill in the art to make plug 58 of the device disclosed by

Stapleton et al. self-sealing so that reagents and samples can be added to chamber 32 without exposing the chamber to the exterior environment. It also would have been obvious to one of ordinary skill in the art to provide the device disclosed by Stapleton et al. with an automated dispenser comprising a conduit having a piston therein for puncturing sealed containers so that the dispensing of samples and reagents into the chamber 32 of the device can be automated. See In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), a case in which the Court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is considered an obvious expedient.

***Response to Arguments***

Applicant's arguments regarding the rejection of claims 1-4, 10, 12, 13, 17 and 18 have been fully considered but they are not persuasive.

In regards to Applicants' argument that the flexible bladder 60 disclosed by Stapleton is not a valve, the Stapleton reference discloses that bladder 60 of plug 58 is flexible and that the deformation of the bladder 60 allows chamber 32 to be vented (see lines 1-16, col. 12). It is the Office's stance that any structure that controls the flow of a fluid within a conduit can be considered a valve.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PSH  
5/10/06

  
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